

46

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: JAMES CHEN  
Serial No.: 09/905,405  
Filed: July 13, 2001  
For: *COMPOSITIONS AND METHODS FOR  
TREATMENT OF METABOLIC BONE  
DISORDERS AND BONE METASTASES*

Art Unit: 3764  
Examiner: Unassigned

RECEIVED  
FEB 21 2002  
TECHNOLOGY CENTER 3700

TRANSMITTAL LETTER

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Transmitted herewith via hand delivery are a Supplemental Information Disclosure Statement, Form PTO-1449 (4 pages) and cited references for filing in connection with the above-identified application. Because this Information Disclosure Statement is filed prior to receipt of a first Office Action on the merits in the above-referenced application, no fee is due. However, should it be determined that a fee for filing these papers is required, the Commissioner is authorized to charge Deposit Account Number 50-1213, as stated below:

- (X) The Commissioner is hereby authorized to charge the fee for the Information Disclosure Statement and any other fees that may be due under 37 C.F.R. §§1.16-1.17 in connection with this paper or with this application during its entire pendency to Deposit Account No. 50-1213. A duplicate of this sheet is enclosed.

Respectfully submitted  
HELLER, EHRMAN, WHITE & McAULIFFE

By:

Stephanie L. Seidman  
Registration No. 33,779

RECEIVED  
FEB 22 2002  
TC 3700 MAIL ROOM

Date: February 20, 2002  
Attorney Docket No.: 25886-0060  
Address all correspondence to:  
Stephanie L. Seidman, Esq.  
HELLER, EHRMAN, WHITE & McAULIFFE  
Stephanie L. Seidman  
4350 La Jolla Village Drive, 7th Floor  
San Diego, California 92122-1246  
Telephone: (858) 450-8400  
Facsimile: (858) 587-5360  
EMAIL: sseidman@hewm.com

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: **JAMES CHEN**  
Serial No.: 09/905,405  
Filed: July 13, 2001  
For: *COMPOSITIONS AND METHODS  
FOR TREATMENT OF  
METABOLIC BONE DISORDERS  
AND BONE METASTASES*  
Art Unit: 3764  
Examiner: Unassigned

RECEIVED  
FEB 21 2002  
TECHNOLOGY CENTER 3700

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE  
WITH 37 C.F.R. §§ 1.97-1.98**

Commissioner for Patents  
Washington, D.C. 20231

RECEIVED  
FEB 22 2002  
TECH 3700 MAIL ROOM

Dear Sir:

Since this Supplemental Information Disclosure Statement is filed before the receipt of a first Office Action on the merits for the above-captioned application, no filing fee is due. If it is determined that a fee is due, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-1213.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. The Forms PTO-1449 (4 pages) and cited references are provided herewith.

The documents listed on the Forms PTO-1449 and supplied herewith are in the English language. Hence, in accordance with the requirements of 37 C.F.R.

**U.S.S.N. 09/905,405**  
**CHEN**  
**Supplemental IDS**

§1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Applicant also makes known to the Office the following U.S. and International applications, which are commonly owned and/or have one or more inventors in common with the instant application.

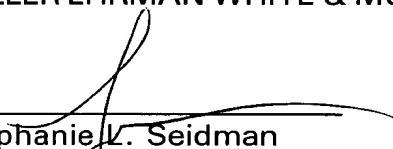
| <u>U.S.S.N.(App. no.)</u> | <u>Filing Date</u> | <u>Docket No.</u> |
|---------------------------|--------------------|-------------------|
| 09/232,129                | 01/15/99           | 0054              |
| 09/271,575                | 03/18/99           | 0055              |
| 09/905,501                | 07/13/01           | 0055B             |
| 09/905,777                | 07/13/01           | 0057              |
| 09/386,692                | 08/31/99           | 0061              |
| 09/760,362                | 01/12/01           | 0062              |
| 09/798,277                | 03/02/01           | 0066              |
| 09/739,155                | 12/18/00           | 0048              |
| 09/592,150                | 06/12/00           | 0049              |
| 60/289,750                | 05/09/01           | P0051             |
| 60/351,460                | 01/23/02           | P0052             |

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing references and information and that they be made of record in the file history of the above-captioned application.

U.S.S.N. 09/905,405  
CHEN  
Supplemental IDS

Respectfully submitted,  
HELLER EHRMAN WHITE & MCAULIFFE LLP

By:   
Stephanie L. Seidman  
Registration No. 33,779

**Dated: February 20, 2002**  
Attorney Docket No. 25886-0060  
**Address all correspondence to:**  
Stephanie L. Seidman, Esq.  
Heller Ehrman White & McAuliffe LLP  
4350 La Jolla Village Drive, 7th Floor  
San Diego, CA 92122-1246  
Telephone: (858) 450-8400  
Facsimile: 858/587-5360  
EMAIL sseidman@HEWM.com

|                          |                                |                          |
|--------------------------|--------------------------------|--------------------------|
| FORM PTO-1449 (Modified) | ATTY. DOCKET NO.<br>25886-0060 | SERIAL NO.<br>09/905,405 |
|                          | APPLICANT<br>Chen, James       |                          |
|                          | FILING DATE<br>July 13, 2001   | GROUP<br>unassigned      |

LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE  
STATEMENT

U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL |    | DOCUMENT NUMBER |   |   |   |   |   |   | DATE     | NAME                    | CLASS | SUB<br>CLASS | FILING<br>DATE |
|---------------------|----|-----------------|---|---|---|---|---|---|----------|-------------------------|-------|--------------|----------------|
|                     | AA | 4               | 9 | 3 | 2 | 9 | 3 | 4 | 06/12/90 | Dougherty <i>et al.</i> |       |              |                |
|                     | AB | 5               | 0 | 0 | 2 | 9 | 6 | 2 | 03/26/91 | Pandey <i>et al.</i>    |       |              |                |
|                     | AC | 5               | 1 | 7 | 1 | 7 | 4 | 9 | 12/15/92 | Levy                    |       |              |                |
|                     | AD | 5               | 2 | 8 | 3 | 2 | 5 | 5 | 02/01/94 | Levy <i>et al.</i>      |       |              |                |
|                     | AE | 5               | 3 | 1 | 4 | 9 | 0 | 5 | 05/24/94 | Pandey <i>et al.</i>    |       |              |                |
|                     | AF | 5               | 3 | 9 | 9 | 5 | 8 | 3 | 03/21/95 | Levy <i>et al.</i>      |       |              |                |
|                     | AG | 5               | 4 | 4 | 5 | 6 | 0 | 8 | 08/29/95 | Chen <i>et al.</i>      |       |              |                |
|                     | AH | 5               | 4 | 7 | 4 | 7 | 6 | 5 | 12/12/95 | Thorpe                  |       |              |                |
|                     | AI | 5               | 4 | 8 | 2 | 6 | 9 | 8 | 01/09/96 | Griffiths               |       |              |                |
|                     | AJ | 5               | 4 | 8 | 4 | 7 | 7 | 8 | 01/16/96 | Kenney <i>et al.</i>    |       |              |                |
|                     | AK | 5               | 4 | 8 | 4 | 8 | 0 | 3 | 01/16/96 | Richter                 |       |              |                |
|                     | AL | 5               | 6 | 3 | 0 | 9 | 9 | 6 | 05/20/97 | Reno <i>et al.</i>      |       |              |                |
|                     | AM | 5               | 7 | 0 | 2 | 4 | 3 | 2 | 12/30/97 | Chen <i>et al.</i>      |       |              |                |
|                     | AN | 5               | 7 | 0 | 5 | 5 | 1 | 8 | 01/06/98 | Richter <i>et al.</i>   |       |              |                |
|                     | AO | 5               | 7 | 3 | 6 | 5 | 6 | 3 | 04/07/98 | Richter                 |       |              |                |
|                     | AP | 5               | 7 | 6 | 6 | 2 | 3 | 4 | 06/16/98 | Chen <i>et al.</i>      |       |              |                |
|                     | AQ | 5               | 7 | 7 | 0 | 7 | 3 | 0 | 06/23/98 | Pandey <i>et al.</i>    |       |              |                |
|                     | AR | 5               | 7 | 8 | 2 | 8 | 9 | 6 | 07/21/98 | Chen <i>et al.</i>      |       |              |                |
|                     | AS | 5               | 8 | 0 | 0 | 4 | 7 | 8 | 09/01/98 | Chen <i>et al.</i>      |       |              |                |
|                     | AT | 5               | 8 | 2 | 7 | 1 | 8 | 6 | 10/27/98 | Chen <i>et al.</i>      |       |              |                |
|                     | AU | 5               | 8 | 2 | 9 | 4 | 4 | 8 | 11/03/98 | Fisher <i>et al.</i>    |       |              |                |
|                     | AV | 5               | 8 | 6 | 4 | 0 | 3 | 5 | 01/26/99 | Pandey <i>et al.</i>    |       |              |                |
|                     | AW | 5               | 8 | 8 | 2 | 3 | 2 | 8 | 03/16/99 | Levy <i>et al.</i>      |       |              |                |
|                     | AX | 5               | 9 | 1 | 3 | 8 | 8 | 4 | 06/22/99 | Trauner <i>et al.</i>   |       |              |                |

RECEIVED  
FEB 22 2002  
MAIL ROOM  
3764  
3700

|          |                 |
|----------|-----------------|
| EXAMINER | DATE CONSIDERED |
|----------|-----------------|

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Title: **COMPOSITIONS AND METHODS FOR TREATMENT OF METABOLIC BONE DISORDERS AND BONE METASTASES**

Mail date: 02/20/02

|                          |                                |                          |
|--------------------------|--------------------------------|--------------------------|
| FORM PTO-1449 (Modified) | ATTY. DOCKET NO.<br>25886-0060 | SERIAL NO.<br>09/905,405 |
|                          | APPLICANT<br>Chen, James       |                          |
|                          | FILING DATE<br>July 13, 2001   | GROUP<br>unassigned      |

LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE  
STATEMENT

U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL |    | DOCUMENT NUMBER |   |   |   |   |   |   | DATE     | NAME                   | CLASS | SUB<br>CLASS | FILING<br>DATE |
|---------------------|----|-----------------|---|---|---|---|---|---|----------|------------------------|-------|--------------|----------------|
|                     | AY | 5               | 9 | 5 | 2 | 3 | 6 | 6 | 09/14/99 | Pandey <i>et al.</i>   |       |              |                |
|                     | AZ | 6               | 0 | 1 | 5 | 8 | 9 | 7 | 01/18/00 | Theodore <i>et al.</i> |       |              |                |
|                     | BA | 6               | 0 | 5 | 8 | 9 | 3 | 7 | 05/09/00 | Doiron <i>et al.</i>   |       |              |                |
|                     | BB | 6               | 0 | 8 | 3 | 4 | 8 | 5 | 07/04/00 | Licha <i>et al.</i>    |       |              |                |
|                     | BC | 6               | 1 | 0 | 3 | 7 | 5 | 1 | 08/15/00 | Pandey <i>et al.</i>   |       |              |                |
|                     | BD | 6               | 2 | 1 | 7 | 8 | 6 | 9 | 04/17/01 | Meyer <i>et al.</i>    |       |              |                |

FOREIGN PATENT DOCUMENTS

|  |    | DOCUMENT NUMBER |   |   |   |   |   |   | DATE     | COUNTRY | CLASS | SUB<br>CLASS | Translation<br>Yes No |  |
|--|----|-----------------|---|---|---|---|---|---|----------|---------|-------|--------------|-----------------------|--|
|  | BE | 0               | 1 | 7 | 5 | 6 | 1 | 7 | 03/26/86 | EP      |       |              |                       |  |
|  | BF | 9               | 3 | 0 | 0 | 0 | 0 | 5 | 01/07/93 | PCT     |       |              |                       |  |
|  | BG | 9               | 3 | 2 | 4 | 1 | 2 | 7 | 12/09/93 | PCT     |       |              |                       |  |
|  | BH | 9               | 4 | 0 | 6 | 4 | 2 | 4 | 03/31/94 | PCT     |       |              |                       |  |
|  | BI | 9               | 5 | 3 | 2 | 0 | 0 | 1 | 11/30/95 | PCT     |       |              |                       |  |
|  | BJ | 9               | 7 | 4 | 0 | 6 | 7 | 9 | 11/06/97 | PCT     |       |              |                       |  |
|  | BK | 9               | 7 | 4 | 6 | 2 | 6 | 2 | 12/11/97 | PCT     |       |              |                       |  |
|  | BL | 9               | 8 | 5 | 2 | 6 | 1 | 0 | 11/26/98 | PCT     |       |              |                       |  |

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

|  |    |  |
|--|----|--|
|  | BM | Chen, J. "Next Generation Light Delivery System for Multi-Treatment Extended Duration Photodynamic Therapy (MED-PDT), <i>SPIE-Proceedings Series</i> , 2972:161-167 (1997)   |
|  | BN | Dillon <i>et al.</i> , "In Vitro and In Vivo Protection Against Phototoxic Side Effects of Photodynamic Therapy by Radioprotective Agents WR-2721 and WR-77913", <i>Photochem. Photobiol.</i> , 48(2):235-238 (1988) |
|  | BO | Dougherty <i>et al.</i> , <u>Yearly Review</u> "Photodynamic Therapy", <i>Photochem. Photobiol.</i> , 58(6):895-900 (1993)   |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Title: **COMPOSITIONS AND METHODS FOR TREATMENT OF METABOLIC BONE DISORDERS AND BONE METASTASES**

Mail date: 02/20/02

|   |                                |                          |
|---|--------------------------------|--------------------------|
| FORM PTO-1449 (Modified)  | ATTY. DOCKET NO.<br>25886-0060 | SERIAL NO.<br>09/905,405 |
| LIST OF PATENTS AND PUBLICATIONS FOR<br>APPLICANT'S INFORMATION DISCLOSURE<br>STATEMENT | APPLICANT<br>Chen, James       |                          |
|   | FILING DATE<br>July 13, 2001   | GROUP<br>unassigned      |

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

|  |    |   |
|--|----|---|
|  | BP | Dougherty <i>et al.</i> , <u>Review</u> "Photodynamic Therapy", <i>J. Natl. Cancer Inst.</i> , <u>90</u> (12):889-905 (1998)  |
|  | BQ | Fisher, W.G. <i>et al.</i> "Simultaneous Two-Photon Activation of Type-1 Photodynamic Therapy Agents," <i>Photochem. Photobiol.</i> , <u>66</u> (2):141-155 (1997)  |
|  | BR | Mew <i>et al.</i> , "Photoimmunotherapy: Treatment of animal Tumors with Tumor-Specific Monoclonal Antibody-Hematoporphyrin Conjugates", <i>J. Immunol.</i> , 130(3):1473-1477 (1983).  |
|  | BS | Millson, C.E. <i>et al.</i> "Ex-Vivo Treatment of Gastric Helicobacter Infection by Photodynamic Therapy," <i>J. Photochem. Photobiol. B: Biol.</i> , <u>32</u> :59-65 (1996)   |
|  | BT | Pandey <i>et al.</i> , "Alkyl Ether Analogs of Chlorophyll- <i>a</i> , Derivatives: Part 1. Synthesis, Photophysical Properties and Photodynamic Efficacy", <i>Photochem. Photobiol.</i> , <u>64</u> (1):194-204 (1996)               |
|  | BU | Pandey <i>et al.</i> , "Comparative <i>in vivo</i> Sensitizing Efficacy of Porphyrin and Chlorin Dimers Joined with Ester, Ether, Carbon-Carbon or Amide Bonds", <i>J. Molecular Recognition</i> , <u>9</u> :118-122 (1996)           |
|  | BV | Pandey <i>et al.</i> , "Chlorin And Porphyrin Derivatives As Potential Photosensitizers In Photodynamic Therapy", <i>Photochem. Photobiol.</i> , <u>53</u> (1):65-72 (1991)   |
|  | BW | Pandey <i>et al.</i> , "Shedding some light on tumours", <i>Chem. Indust.</i> , <u>1998</u> :739-743, (1998)  |
|  | BX | Pandey <i>et al.</i> , "Syntheses Of New Bacteriochlorins And Their Antitumor Activity", <i>Bioorganic Med. Chem. Lett.</i> , <u>4</u> (10):1263-1267 (1994)  |
|  | BY | Pandey <i>et al.</i> , "Synthesis, Photophysical Properties, <i>in Vivo</i> Photosensitizing Efficacy, and Human Serum Albumin Binding Properties of Some Novel Bacteriochlorins", <i>J. Med. Chem.</i> , <u>40</u> :2770-2779 (1997) |
|  | BZ | Ruebner, A. <i>et al.</i> "Carrier Systems in PDT II: Accumulation Strategies of Biotin-Avidin Coupled Photosensitizers Developed On Cultured Tumor Cells," <i>SPIE</i> , <u>2625</u> :328-32 (1996)                                  |
|  | CA | Savitsky, A.P. <i>et al.</i> "Avidin-Biotin System for Targeting Delivery of Photosensitizers and Other Cytotoxic Agents Into Malignant Tissues," <i>SPIE</i> , <u>3191</u> : 243-53 (1997)   |
|  | CB | Sigsestad, C.P. <i>et al.</i> "Chemical Modification of Normal Tissue Damage Induced by Photodynamic Therapy," <i>Brit. J. Cancer</i> <u>74</u> (Suppl.37):S89-92 (1996)  |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Title: **COMPOSITIONS AND METHODS FOR TREATMENT OF METABOLIC BONE DISORDERS AND BONE METASTASES**

Mail date: 02/20/02

|                          |                                |                          |
|--------------------------|--------------------------------|--------------------------|
| FORM PTO-1449 (Modified) | ATTY. DOCKET NO.<br>25886-0060 | SERIAL NO.<br>09/905,405 |
|                          | APPLICANT<br>Chen, James       |                          |
|                          | FILING DATE<br>July 13, 2001   | GROUP<br>unassigned      |

LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE  
STATEMENT

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

|    |  |
|----|--|
| CC | Wieman, T.J., "Photodynamic Therapy (PDT) of locally recurrent breast cancer (LRBC) with lutetium texaphyrin (Lutrin): a phase IB/IIA trial", <i>Program/Proceedings of Am. Soc. Clin. Oncol.</i> , <u>18</u> :111a 35th Annual Meeting, Atlanta, Georgia, Abstract No. 418 (1999) |
| CD | Wilder-Smith <i>et al.</i> , "Photoeradication of helicobacter pylori in humans: phase I study", <i>AGA Abstracts: Gastroenterol.</i> , <u>116</u> (4):A354, Abstract No. G1546 (1999)   |

RECEIVED  
FEB 22 2002  
3700 MAIL ROOM

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Title: **COMPOSITIONS AND METHODS FOR TREATMENT OF METABOLIC BONE DISORDERS AND BONE METASTASES**

Mail date: 02/20/02